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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

24

DATE MAILED: 02/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/538,709

Examiner

Regina M. DeBerry

Applicant(s)

CERRETTI, DOUGLAS P.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-648)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other _____

Status of Application, Amendments and/or Claims

The amendment filed 25 November 2002 (Paper No. 23) has been entered in full. New claims 58-61 have been added. Claims 29-61 are under examination.

Priority to application 08/318,393 under 35 U.S.C 120 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejections of claims 29-52 under 35 U.S.C. 102(e) as being anticipated by Flanagan *et al.*, U.S. Patent Number 6,268,476 B1 as set forth at pages 3-4 of the previous Office Action (17 May 2002, Paper No. 21) is *withdrawn* in view of Applicant's arguments (25 November, Paper No. 23).

Specification

The disclosure is objected to because of the following informalities:

The specification contains an incorrect description of murine LERK-6. The specification teaches the nucleic acid sequence of murine LERK-6 as SEQ ID NO:1 and the amino acid sequence of murine LERK-6 as SEQ ID NO:2.

A clarification was requested in the last Office Action because of the discrepancy between the amino acid sequence of murine LERK-6 recited in the Cerretti Declaration under 37 CFR 1.131 and the amino acid sequence of murine LERK-6 recited in SEQ ID NO:2 of the sequence listing.

Applicant's explanation does not resolve the inconsistency. Contrary to Applicant's assertion, the discrepancy is relevant because the instant claims are drawn

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to DNA encoding murine LERK-6 polypeptide. The description states that the term "LERK-6" encompasses polypeptides having the amino acid sequence 1-184 of SEQ ID NO:2 (murine LERK-6). The first three amino acids of SEQ ID NO:2 are **Ala Arg Asn**. This is inconsistent with the evidence stated in the 1.131 declaration. The first three amino acids of murine LERK-6 according to the 1.131 declaration are **Ala Asn Ala**. SEQ ID NO:2 as recited in the instant specification is a chimeric protein comprising two amino acids from the vector and the amino acids comprising murine LERK-6. The instant specification is objected to because it contradicts the definition of murine LERK-6 as recited in the Cerretti declaration.

Applicant's attention is directed to Ex Parte Maizel 27USPQ2d 1662 (BPAI 1993), wherein the board discusses how to correct errors in sequence listings.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA that encodes a polypeptide that is at least 80% identical to the polypeptide of SEQ ID NO:2, wherein said polypeptide binds hek/elk, does not reasonably provide enablement for an isolated DNA that encodes a polypeptide that is at least 80% identical to the polypeptide of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims are generally drawn to an isolated DNA that encodes a polypeptide that is at least 80% identical to the polypeptide of SEQ ID NO:2. The instant claims are not enabled because there is no functional limitation in the claims. The specification states that the instant polypeptide binds the hek/elk receptor.

There are no working examples of polypeptides less than 100% identical to the polypeptide SEQ ID NO:2. The skilled artisan would not know how to use non-identical polypeptides on the basis of teachings in the prior art or specification unless they possessed the function disclosed in the instant specification. While the specification generally describes properties of cytokines, it is acknowledged that cytokines are diverse in function and structure (see Ozaki *et al.*, J. Biol. Chem., 2002 and Haddad, Biochem. and Biophys. Res. Comm., 2002). The specification does not provide guidance for using polypeptides related to (*i.e.*, 80%-99% identity) but not identical to the amino acids of SEQ ID NO:2 which do not have the specific disclosed activity shown for murine LERK-6 (binding hek/elk receptor). The claims are broad because they do not require the claimed polypeptide to be identical to the disclosed sequence and because the claims have no functional limitation.

For these reasons, which include the complexity and unpredictability of the nature of the invention and art in terms of the diversity of cytokines and lack of knowledge about function(s) of encompassed polypeptides structurally related to SEQ ID NO:2, the lack of working examples of polypeptides less than 100% identical to the

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polypeptide of SEQ ID NO:2, the lack of direction or guidance for using polypeptides that are not identical to SEQ ID NO:2, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112, Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-57 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-57 are generally drawn to an isolated molecule encoding LERK-6 polypeptide that binds hek/elk, wherein said polypeptide comprises amino acids of SEQ ID NO:2 and recombinant phage λ .gt10 vector clone λ .13M LERK-6 having ATCC No. 75829. The instant claims are indefinite because SEQ ID NO:2 is a chimeric protein not murine LERK-6 polypeptide.

Claim 61 is indefinite because it is drawn to an isolated DNA selected from the group consisting of: DNA that hybridizes under highly stringent conditions to the DNA of SEQ ID NO:1, and which DNA encodes a polypeptide that binds hek/elk.

DNA that hybridizes under highly stringent conditions to the nucleotides 1-402 of SEQ ID NO:1, and which DNA encodes a polypeptide that binds hek/elk.

DNA that hybridizes under highly stringent conditions to nucleotides 1-435 of SEQ ID NO:1 and which DNA encodes a polypeptide that binds hek/elk. Stringency is relative, and the art does not recognize a single set of conditions as stringent. The specification also does not provide an unambiguous definition for the term. In the absence of a recitation of clear hybridization conditions (e.g., "hybridizes at wash conditions of A X SSC and B % SDS at CoC"), the claims fail to define the metes and bounds of the varying structures of polynucleotides recited in the claimed methods.

Claim Rejections - 35 USC § 102(e)

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 29-52 and 58-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Flanagan *et al.*, U.S. Patent No. 5,795,734.

The instant claims are generally drawn to the isolated DNA encoding a LERK-6 polypeptide that binds hek/elk, wherein said polypeptide comprises amino acids 1-184 of SEQ ID NO:2

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In the patent of Flanagan, claim 1 is drawn to an isolated nucleic acid encoding a recombinant polypeptide, which polypeptide comprises an Elf-1 polypeptide sequence at least 70 percent identical to an amino acid sequence selected from the group consisting of SEQ ID Nos 2 and 4, and portions thereof, and which Elf-polypeptide specifically binds to an EPH-type receptor. Flanagan claims the DNA encoding SEQ ID NO:2. Flanagan's SEQ ID NO:2 is 100% identical to SEQ ID NO:2 of the instant claims. Amino acid residue numbers 26-209 in SEQ ID NO:2 of Flanagan is 100% identical to amino acid residue numbers 1-184 in SEQ ID NO:2 in the instant application. Please see reference, SEQ ID NO:2, columns 71-74.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Zimmerman

RMD

RMD

January 30, 2003